

## CLAIMS

What is claimed is:

- 5        1.        A pharmaceutical composition for treating and/or preventing a disease, disorder and/or condition of the respiratory system due to expression of a gene regulated by NF- $\kappa$ B, comprising an NF- $\kappa$ B decoy and a pharmaceutically acceptable carrier.
- 10       2.        A composition according to Claim 1, wherein said NF- $\kappa$ B decoy is a NF- $\kappa$ B decoy or a derivative, variant or fragment thereof, and the derivative, variant or fragment has a biological activity.
- 15       3.        A composition according to Claim 1, wherein said NF- $\kappa$ B decoy is a decoy set forth in SEQ. ID NO: 1.
- 20       4.        A composition according to Claim 1 wherein said disease, disorder and/or condition of respiratory system is airway inflammatory disease, airway stenosis or nasal cavity inflammatory disease.
- 25       5.        A composition according to Claim 1, wherein said disease, disorder and/or condition of the respiratory system is COPD, asthma or rhinitis.
- 30       6.        A composition according to Claim 1, wherein said disease, disorder and/or condition of the respiratory system is COPD.
7.        A composition according to Claim 1, wherein said disease, disorder and/or condition of the respiratory

system is asthma.

8. A composition according to Claim 1, wherein said disease, disorder and/or condition of the respiratory system is rhinitis.

9. A composition according to Claim 1, wherein said pharmaceutically acceptable carrier is a hydrophilic polymer, a carbohydrate or an insoluble additive.

10. A composition according to Claim 1, wherein said pharmaceutically acceptable carrier is at least one type selected from the group consisting of a liposome, lactose, trehalose, sucrose, mannitol and xylitol.

11. A composition for treating and/or preventing a disease, disorder and/or condition of the respiratory system relating to an eosinophil abnormality, comprising NF- $\kappa$ B decoy and a pharmaceutically acceptable carrier.

12. A composition according to Claim 11, wherein said NF- $\kappa$ B decoy is a NF- $\kappa$ B decoy or a derivative, variant or fragment thereof, and the derivative, variant or fragment has a biological activity.

13. A composition according to Claim 11, wherein said NF- $\kappa$ B decoy is a decoy set forth in SEQ. ID NO: 1.

14. A composition according to Claim 11 wherein said disease, disorder and/or condition of the respiratory system is airway inflammatory, airway stenosis or nasal cavity inflammatory disease, disorder and/or condition.

15. A composition according to Claim 11, wherein said disease, disorder and/or condition of the respiratory system is COPD, asthma or rhinitis.

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16. A composition according to Claim 11, wherein said disease, disorder and/or condition of the respiratory system is an asthma selected from the group consisting of bronchial asthma, infantile asthma, allergic asthma, atopic asthma, steroid refractory asthma, non-allergic asthma, endogenous asthma, exogenous asthma, aspirin asthma, cardiac asthma and infectious asthma; or a rhinitis selected from the group consisting of allergic rhinitis, pollinosis, acute rhinitis, chronic rhinitis, hypertrophic rhinitis, chronic sinusitis (emphysema) and deflected septum.

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17. A composition according to Claim 11, wherein said pharmaceutically acceptable carrier is a hydrophilic polymer or a carbohydrate.

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18. A composition according to Claim 11, wherein said pharmaceutically acceptable carrier is one or more selected from the group consisting of a liposome, lactose, trehalose, sucrose, mannitol and xylitol.

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19. A dosage formulation for respiratory system adapted for administration to the respiratory system, comprising a composition according to any one of Claims 1-18.

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20. A dosage formulation according to Claim 19, wherein said administration to the respiratory system

comprises administration into the airway or transairway absorption.

5        21.     A dosage formulation according to Claim 19, wherein said administration to the respiratory system is administration to the airway by atomization or inspiration.

10       22.     A dosage formulation according to Claim 19, wherein said administration into the airway comprises administration by metered dose inhaler (MDI), dry powder inhaler (DPI) or nebulizer.

15       23.     A dosage formulation according to Claim 19, wherein said composition is provided as a dry powder.

20       24.     A dosage formulation according to Claim 23, wherein said dry powder is a microparticle produced by means of one of selected from the group consisting of a bowl mill, a bead mill, a jet mill, an ultimizer, a mortar, a stonemill, spray drying and supercritical fluid.

25       25.     A dosage formulation according to Claim 23, wherein the dry powder has an aerodynamic average particle size of about 0.01 to about 50 micrometer.

30       26.     A dosage formulation according to Claim 23, wherein the dry powder has an aerodynamic average particle size of about 0.05 to about 30 micrometer.

27.     A dosage formulation according to Claim 23, wherein the dry powder has an aerodynamic average

particle size of about 0.1 to about 10 micrometer.

5 28. A dosage formulation according to Claim 19, wherein a dosage of 10  $\mu$ g to 100 mg per round is provided.

10 29. A dosage formulation according to Claim 19, wherein a dosage of 50  $\mu$ g to 50 mg per round is provided.

30. A dosage formulation according to Claim 19, wherein a dosage of 10 mg or less per round is provided.

15 31. A dosage formulation according to Claim 19, wherein the administration to the respiratory system comprises nasal absorption.

20 32. A dosage formulation according to Claim 31, which is a formulation selected from the group consisting of a nasal drop, a nasal spray agent, an agent for nebulizer, an agent for a respirator and powder administration formulation.

25 33. A dosage formulation according to Claim 31, which is a nasal drop for rhinitis.

30 34. A dosage formulation according to Claim 19, wherein the NF- $\kappa$ B decoy is encapsulated in an HVJ-E envelope vector.

35. A dosage formulation according to Claim 19 wherein the administration to the respiratory system comprises administration to the lung.

36. A device for treating the respiratory system comprising a composition according to any one of Claims 1-18, and means for administering the composition to the respiratory system.

37. A device according to Claim 36, wherein the means for administration to the respiratory system comprises means selected from the group consisting of means for administration to the lung, means for transairway administration, means for transairway absorption and means for nasal absorption.

38. A device according to Claim 36, wherein said means for administration to the airway comprises a metered dose inhaler (MDI), dry powder inhaler (DPI) or a nebulizer.

39. A method for manufacturing a particle comprising NF- $\kappa$ B decoy, comprising the steps of:

- A) providing the decoy and a pharmaceutically acceptable carrier;
- B) drying and heating the decoy and the carrier to a temperature sufficient for particulization; and
- C) obtaining particles having a desired particle size.

40. A method according to Claim 39 wherein the temperature is 50 degree Celcius or lower.

41. A method according to Claim 39 wherein the temperature is 100 degree Celcius or lower.

42. A method according to Claim 39, wherein the dry powder has an aerodynamic average particle size of about 0.01 to about 50 micrometer.

5 43. A method according to Claim 39, wherein the dry powder has an aerodynamic average particle size of about 0.05 to about 30 micrometer.

10 44. A method according to Claim 39, wherein the dry powder has an aerodynamic average particle size of about 0.1 to about 10 micrometer.

15 45. A method for treating and/or preventing a disease, disorder and/or condition of the respiratory system due to expression of a gene regulated by NF- $\kappa$ B, comprising the step of:

A) administration of a composition comprising an NF- $\kappa$ B decoy and a pharmaceutically acceptable carrier to the respiratory system of a subject.

20 46. A method according to Claim 45, wherein said disease, disorder and/or condition of the respiratory system is airway inflammatory disease, airway stenosis or nasal cavity inflammatory disease.

25 47. A method according to Claim 45, wherein said disease, disorder and/or condition of respiratory system is COPD, asthma or rhinitis.

30 48. A method according to Claim 45, wherein said administration to the respiratory system comprises administration into the airway or transairway absorption.

49. A method according to Claim 45, wherein said administration to the respiratory system is administration to the airway by atomization or inspiration.

50. A method according to Claim 45, wherein said administration into the airway comprises administration by metered dose inhaler (MDI), dry powder inhaler (DPI) or nebulizer.

51. A method according to Claim 45, wherein administration is achieved by means selected from the group consisting of a nasal drop, a nasal spray, a nebulizer, a respirator and powder administration.

52. A method for treating and/or preventing a disease, disorder and/or condition of the respiratory system due to an eosinophil abnormality, comprising the step of:

A) administration of a composition comprising an NF- $\kappa$ B decoy and a pharmaceutically acceptable carrier to the respiratory system of a subject.

53. Use of an NF- $\kappa$ B decoy for the manufacture of a medicament for treating and/or preventing a disease, disorder and/or condition of the respiratory system due to expression of a gene regulated by NF- $\kappa$ B.

54. Use of an NF- $\kappa$ B decoy for the manufacture of a medicament for treating and/or preventing a disease, disorder and/or condition of respiratory system due to an eosinophil abnormality.